

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL
INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION

)
) MDL No.1456
)
) Master File No. 01-CV-12257-PBS
) Subcategory No. 06-CV-11337-PBS
)

THIS DOCUMENT RELATES TO:
*U.S. of America ex rel. Ven-A-Care
of the Florida Keys, Inc., et al. v.
Boehringer Ingelheim Corporation, et al.,*
Civil Action No. 07-10248-PBS

) Judge Patti B. Saris
) Magistrate Judge Marianne B. Bowler
)

) **Leave to file granted on November 4, 2009**
)

**THE ROXANE DEFENDANTS' SUPPLEMENTAL
LOCAL RULE 56.1 STATEMENT OF MATERIAL FACTS**

**I. The DMERCs' Drug Classifications And Procedures Were Not Publicly Available,
And Were Unknown To Roxane.**

319. The Cigna and Palmetto Durable Medical Equipment Regional Carriers ("DMERCs") confirmed that the Cigna and Palmetto Medicare pricing arrays, which reflected the classification of Novaplus ipratropium bromide as a brand for most time periods, were not publicly available. (Tab 336, 10/14/09 Stone Dep. 156, Tab 337, 10/16/09 Helton Dep. 76-77; *see also* Tab 338, Roxane SOF ¶ 162)

320. The Cigna and Palmetto DMERCs testified that a manufacturer, like Roxane, would not know that the DMERCs classified Novaplus ipratropium bromide as a brand as opposed to a generic drug. (Tab 337, 10/16/09 Helton Dep. 78-79, 116-18; Tab 336, 10/14/09 Stone Dep. 156)

321. The Palmetto DMERC testified that the DMERCs' "internal procedures," such as the Desk Procedures outlining how to classify drugs by reviewing capitalization formats in the

paper version of Redbook, were also not publicly available (Tab 336, 10/14/09 Stone Dep. 29, 39-40), and were created by Blue Cross/Blue Shield as the Medicare Part B carrier for South Carolina. (*Id.* at 29-31)

322. The DMERCs were allowed by regulation and HCFA directives to use various published compendia such as Redbook, FirstDatabank Bluebook, or Medispan. (Tab 338, Roxane SOF ¶ 163; Tab 337, Helton Dep. 10/16/09 64-65; Tab 336, 10/14/09 Stone Dep. 65-66)

323. In practice, however, the DMERCs limited their review to Redbook, and never looked to other compendia such as FirstDatabank Blue Book or Medispan to determine whether a drug was a brand or a generic. (Tab 337, 10/16/09 Helton Dep. 62-63, 65; *see also* Tab 336, 10/14/09 Stone Dep. 60; Tab 338, Roxane SOF ¶¶ 214-220)

324. The DMERCs' decision to limit their review solely to Redbook was not public and was based on familiarity and a convenience factor. (Tab 336, 10/14/09 Stone Dep. 62-66; *see also* Tab 337, 10/16/09 Helton Dep. 60-61, 115-16)

II. The DMERCs' Classification Of Novaplus Ipratropium Bromide As A Brand Depended On The Format Of The Compendia Reviewed.

325. When compiling drugs into their Medicare pricing arrays, the DMERCs reviewed different versions of the Redbook pricing compendia, including CD-ROM databases and annual and monthly paper editions. (Tab 336, 10/14/09 Stone Dep. 37-38; *see also* Tab 338, Roxane SOF ¶ 166)

326. The Cigna DMERC testified that a manufacturer like Roxane would have no way of knowing which particular format of Redbook the DMERCs used to create their pricing arrays. (Tab 337, 10/16/09 Helton Dep. 115-16)

327. Yet the classification of the Novaplus-label ipratropium bromide products as generics or brands in the DMERC pricing arrays depended on which format (hard copy versus electronic versions) of Redbook the DMERCs reviewed. (*Id.* at 95)

328. The DMERCs' methodology for classifying drugs as a generic or brand based on the paper Redbook was outlined in the Medicare Drug Pricing Procedure applicable to Medicare Part B and DMERC reimbursement. (Tab 338, Roxane SOF ¶¶ 180-81)

329. This methodology required the DMERCs to look at capitalization conventions and formats in the printed paper version of Redbook to determine whether a drug was a brand or generic (the "capitalization rule"). (Tab 336, 10/14/09 Stone Dep. 40-42; Tab 337, 10/16/09 Helton Dep. 44-48, 69-70; Tab 338, Roxane SOF ¶¶ 180-81) This capitalization rule was specific to the paper edition of Redbook. (Tab 336, 10/14/09 Stone Dep. 110-11; Tab 338, Roxane SOF ¶ 182)

330. The Palmetto DMERC testified that under the capitalization rule described in the Medicare Drug Pricing Procedure, the listing of Novaplus ipratropium bromide in the paper version of Redbook would cause her to classify Novaplus ipratropium bromide as a **generic** drug, and not a brand. (Tab 336, 10/14/09 Stone Dep. 47-48; *see also* Tab 338, Roxane SOF ¶¶ 185-210)

331. The Cigna DMERC also testified that under the capitalization rule described in the Medicare Drug Pricing Procedure, the listing of Novaplus ipratropium bromide in the paper version of Redbook would cause her to classify Novaplus ipratropium bromide as a **generic** drug, and not a brand. (Tab 337, 10/16/09 Helton Dep. 49-50, 58-59; *see also* Tab 338, Roxane SOF ¶¶ 185-210)

332. The Palmetto and Cigna DMERCs employed a different protocol when reviewing the CD-ROM version of Redbook. Specifically, the Palmetto and Cigna DMERCs looked to whether the product had some name in addition to or different from the generic chemical name of the drug (the “drug-name methodology”). (Tab 336, 10/14/09 Stone Dep. 49, 110-11, Tab 337, 10/16/09 Helton Dep. 57:9-14)

333. The Palmetto DMERC testified that this methodology of evaluating whether a drug’s name contained the generic chemical compound name was a criteria that the DMERCs developed internally. (Tab 336, 10/14/09 Stone Dep. 67)

334. The hard copy/paper editions of Redbook did not contain the word “Novaplus” anywhere in the listing for ipratropium bromide. (Tab 337, 10/16/09 Helton Dep. 95; Tab 336, 10/14/09 Stone Dep. 134-35; *see also* Tab 338, Roxane SOF ¶¶ 189, 202)

335. The Palmetto and Cigna DMERCs both testified that using the drug-name methodology looking at the paper Redbook would have still led them to classify Novaplus ipratropium bromide as a *generic* drug, and not a brand drug. (Tab 336, 10/14/09 Stone Dep. 135-36; Tab 337, 10/16/09 Helton Dep. 49-50, 57-59)

336. However, the drug-name methodology led to a different classification result for the Novaplus-label ipratropium bromide products when the DMERCs reviewed the Redbook electronic CD-ROMS, rather than the hard copy/paper versions of the Redbook. Both the Cigna and Palmetto DMERCs testified that they classified the Novaplus ipratropium bromide as a brand based on how it was listed on the Redbook CD-ROMs. (Tab 337, 10/16/09 Helton Dep. 95-96)

337. The DMERCs applied their drug-name methodology to the listings on the Redbook CD-ROMs and classified Novaplus ipratropium bromide as a brand even though the

Redbook CD-ROMs used by the DMERCs contained a “generic field indicator” telling the DMERCs that the Redbook compendia classified Novaplus ipratropium bromide as a generic product. (Tab 336, 10/14/09 Stone Dep. 74-77; Tab 337, 10/16/09 Helton Dep. 84-85; Tab 339, Detailed Product Information Screens for Novaplus Ipratropium Bromide (CIGNA-0120-30, CIGNA-0131-41, CIGNA-0142-53, CIGNA-0154-65, CIGNA-0166-77, CIGNA-0178-89, CIGNA-0190-200, CIGNA-0201-11, CIGNA-0212-24, CIGNA-0225-40, CIGNA-0241-55); *see also* Tab, C Roxane SOF ¶ 182)

338. Specifically, the Redbook CD-ROMs that the Cigna and Palmetto DMERCs used contained the following screen applicable to the Novaplus-label ipratropium bromide NDCs, (Tab 339, Detailed Product Information Screens for Novaplus Ipratropium Bromide, at CIGNA 0187):

Red Book(TM) for Windows®

Release: APRIL, 2002

Detailed Product Information

PRODUCT:	IPRATROPIUM BROMIDE-NOVAPLUS
MANUFACTURER:	Roxane
FORM:	SOLUTION
STRENGTH:	0.02%
ROUTE OF ADMIN:	INHALATION
ORANGE BOOK CODE:	AN
ADD'L DESC:	(S.D.V., 5X5, PROTECTAPAK)
GENERIC NAME:	IPRATROPIUM BROMIDE

NDC:	00054-8404-11
SIZE:	2.500 ml 25s
DEA Class:	RX
UNIT DOSE (Y/N):	Y
SINGLE SOURCE (Y/N):	N
REPACKAGER (Y/N):	N
GENERIC (Y/N):	Y

339. The Palmetto DMERC testified that in the situation where the Redbook compendia CD-ROM that the DMERC relied upon classified a drug with a particular title as a

generic drug, that created a potential ambiguity for the DMERCs. (Tab 336, 10/14/09 Stone Dep. 91-92)

340. The Palmetto DMERC testified that certain words appended to a drug name would not trigger its classification as a brand, for example if the title contained a diluent, she might have consulted the medical staff to determine how to classify the drug. (*Id.* at 83-84)

341. Unlike the Palmetto DMERC, the Cigna DMERC testified that she would have applied the drug-name method as an inflexible rule, stating any additional words in the title of a drug that were different from the words “ipratropium bromide”—including words such as Walgreens, CVS, or “this is a generic drug” would lead her to classify a drug as a brand. (Tab 337, 10/16/09 Helton Dep. 98-99)

III. DMERC Testimony Confirms That Novaplus Ipratropium Bromide Never Set Medicare Payment Rates In The Real World.

342. Beginning in 1998, Medicare Part B payments were determined by comparing the median of all generic sources of a drug to the lowest available price for brand sources. (Tab 338, Roxane SOF ¶¶ 159, 174)

343. The Palmetto DMERC testified that Palmetto’s arrays contained a column containing a “G” or “B,” which reflected whether the reimbursement rate for a particular J-code was set by the median of the generic sources, or by the lowest-priced brand source. (Tab 336, 10/14/09 Stone Dep. 22-25; *see also* Tab E, Stone Decl.¶ 12)

344. A “G” in the column indicated that the rate for the drugs under a J-code was set by the median generic price, not the lowest brand price. (Tab 336, 10/14/09 Stone Dep. 26)

345. For all of the quarters in which Novaplus ipratropium bromide was classified as a brand drug by the Palmetto DMERC, the column contained a “G,” indicating that the allowable

reimbursement rates for the pertinent ipratropium bromide J-codes was set by the median of the generic sources of ipratropium bromide. (Tab 336, 10/14/09 Stone Dep. 27-28)

346. Thus, for every quarter that Novaplus ipratropium bromide was classified as a brand drug by Palmetto, Novaplus ipratropium bromide did not set the payment amount for ipratropium bromide in Palmetto's DME region. (*Id.* at 28; *see also* Tab 338, Roxane SOF ¶¶ 151-55 (outlining facts showing that Novaplus ipratropium bromide was rarely if ever reimbursed under Medicare Part B))

Dated: November 4, 2009

Respectfully submitted,

/s/ Eric T. Gortner

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 4, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ Eric T. Gortner
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